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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,727	10/26/2001	John E. Sims	3151-A	9375

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,727	SIMS ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 7* is/are allowed.

6)☒ Claim(s) *5, 6, and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Request filed on 02/25/2005 for Continued Examination (RCE) under 37 CFR 1.114 of Application 10/061,727 is granted. An action on the RCE follows.

The amendment filed on 02/25/2005 has been entered in full. Claim 5 has been amended. Claims 1, 2, 5-7, and 9-11 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. §112, 1st paragraph, as set forth at pages 3-6 of the previous office action (Paper No. 8, May 29, 2003) has been withdrawn in view of amended claims and Applicants arguement.

The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. §102(b) as being anticipated by Huang et al. (*Proc. Natl. Acad. Sci. USA* 94:12829-12832, 1997), as set forth at pages 10-11 of the previous office action (Paper No. 8, mailed on 05/29/2003), has been withdrawn in view of amended claims.

The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. §102(b) as being anticipated by Cao (US Patent No. 6,280,955, August 28, 2001; 102 (e) date: December 16, 1997), as set forth at page 11 of the previous office action (Paper No. 8, mailed on 05/29/2003), has been withdrawn in view of amended claims.

Claim Rejections under 35 USC § 101

(i) 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii) Claim 9 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter, a host cell comprising the vector of claim 6, which reads on a transgenic human. It is suggested that the claim be amended as "an isolated host cell comprising the vector of claim 6" to overcome this rejection.

Claim Rejections under 35 USC § 1 12, 1st paragraph (Written Description)

Claims 5, 6, 9, and 10 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification discloses human interleukin-1 receptor accessory protein (IL-1R AcP) set forth in SEQ ID NO: 2 and polynucleotides encoding the proteins set forth in SEQ ID NO: 1. The native human IL-1R AcP includes a polymorphism that is present at about a

50/50 ratio. The polymorphism exists as an A at position 1792 of SEQ ID NO: 1, or a C at position 1792 of SEQ ID NO: 1. This results in a Thr at position 598 of SEQ ID NO: 2, or a Pro at position 598 of SEQ ID NO: 2. The specification further discloses that the IL-R AcP polypeptides and polynucleotides of this invention are an alternatively spliced variant of IL-1R AcP in which part of the C-terminal of the cytoplasmic domain is relaced by an alternative peptide sequence. At least part of this alternative peptide sequence is amino acids 449-687of SEQ ID NO: 2 (page 6 of the specification). The disclosure also discloses two additional preferred fragments of SEQ ID NO: 2, amino acids 384-687 of SEQ ID NO: 2 and amino acids 379-687 of SEQ ID NO: 2, which applicants assert are capable of interacting with a signal transduction factor (pages 9 to 10).

However, claim 5, d), recites an isolated polynucleotide comprising a polynucleotide that encodes a fragment of a polypeptide described in a)–c), wherein the fragment interacts with an IL-1R signal transduction facotr; claim 5, g), recites an isolated polynucleotide comprising a polynucleotide that is degenerate to any of the polynucleotides of a), b), c), e), f). Thus, the claim encompasses an enormous genus of nucleic acids that vary substantially both in length and in nucleic acid composition. Claims 6, 9, and 10 depend from claim 5.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial

structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, while parts a), b), c), e), and f) of claim 5 satisfy the written description requirement, parts d) and g) of the claim do not comply with the written description requirement. Claim 5, d), as written, does not require a fragment of a polypeptide described in a)–c) to be derived from the amino acid residues 384-687 of SEQ ID NO: 2, amino acid residues 379-687 of SEQ ID NO: 2, or amino acid residues 449-687 of SEQ ID NO: 2, since parts a), b), and c) recite "comprising", which is an open language. Moreover, part g) recites, in part, a polynucleotide that is degenerate to e), i.e., a variant of a polynucleotide that encodes amino acid residues 449-687 of SEQ ID NO: 2. The instant disclosure of a polynucleotide of SEQ ID NO: 1 is not sufficient to support the claimed genus: i.e., polynucleotides that are degenerate to the variants of the polynucleotide that encodes amino acid residues 449-687 of SEQ ID NO: 2.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to

practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the disclosed polynucleotides, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections under 35 USC § 1 12, 2nd paragraph

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are indefinite because it is unclear what protein is to be made by the process; the claims, as written, read on any proteins produced by a host cell.

From the bottom of page 7 to the middle of page 8, citing case, law, Applicants argue that claim 10 recites a process of preparing a polypeptide by culturing a host cell of claim 9 under conditions promoting expression of the polypeptide. The host cell of claim 9 comprises a vector that includes a polynucleotide of claim 5. Similarly, claim 11 is a process for preparing a polypeptide by culturing a host cell transformed with a vector

that contains a polynucleotide that encodes the polypeptide of SEQ ID NO: 2. This has been fully considered, but is not deemed to be persuasive because the host cell recited in the claims not only express the polypeptide of SEQ ID NO: 2, but also express endogenous polypeptides. Since neither the preamble nor the body of the claims indicates what protein is to be made by the process, the claims are indefinite.

Conclusion

Claims 1, 2, and 7 are allowed. Claims 5, 6, and 9-11 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
April 18, 2005